REMARKS

With the current cancellation of claims 1-3, 5-7, 8-10, 19, 31, 37-40 and 52, and the addition of claims 84-85, claims 18, 35 and 53-85 are pending.

The amendment to claim 18 is supported at least by claim 1 as filed. The deletion of "Form I" and "Form II" and the insertion of the characteristic PXRD peaks for these two crystalline forms of famciclovir in the claims is supported at least by claims 1 and 8 as filed, respectively. Applicants submit that these amendments would not narrow the scopes of the amended claims.

Descriptive support for the new claims 84 and 85 can be found in claims 30 and 31 as filed, respectively.

Claims Allowed

The applicants would like to thank Examiner Berch for holding that claims 57, 59-73 and 79-83 were allowed.

Claim Rejections -- 35 U.S.C. 112, First Paragraph

Applicants respectfully traverse the rejection of claim 35 for failing to comply with the enablement requirement. The non-enablement rejection was made based on the argument that because Brand et al. (1999), *Tetrahedron* 55:5239-5252, discloses that the recrystallization of famciclovir from aqueous acetone allegedly resulted in famciclovir, not a famciclovir monohydrate, the process of claim 35 was not enabled except for the use of aqueous DMF as shown in the example of the current specification. Applicants will file a Rule 132 Declaration shortly to demonstrate that experimental reproduction of the recrystallization procedure of Brand et al., in particular the recrystallization of famciclovir from a water:acetone (50:50, v/v) mixture in the paragraph bridging pages 5250 and 5251, yielded famciclovir monohydrate, not famciclovir. In Experiment 6 of the Rule 132 Declaration to be filed, recrystallization of famciclovir from a water:acetone (50:50, v/v) mixture resulted in a wet solid which was determined to be famciclovir monohydrate based on the powder X-ray diffractogram. When the wet famciclovir monohydrate was dried in a vacuum oven at 45°C overnight, a dried solid was obtained which was an unknown solid form of famciclovir, which was not famciclovir monohydrate, famciclovir Form I, famciclovir Form II. Since Brand did not specify that the solid famciclovir produced via recrystallization was dried in a hot vacuum oven (see the top part of page 5251), Experiment of the Rule 132 Declaration will show that the solid famciclovir obtained by Brand was the famciclovir monohydrate. Thus, the recrystallization procedure of

Brand et al. produced famciclovir monohydrate from the use of aqueous acetone. There would be no reason to assume that using any one of the aqueous solvents in the Markush group of claim 35 would fail to prepare famciclovir monohydrate. Withdrawal of the non-enblement rejection is requested.

Claim Rejections -- 35 U.S.C. §102

(A) Applicants respectfully traverse the anticipatory rejection of claim 35 over Harnden 1990 (*Nucleosides & Nucleotides* (1990) 9:499-513). The Examiner interpreted claim 35 to include the use of a methanol/water mixture, even if the mixture contains only a tiny amount of methanol. Harnden 1990 discloses that a famciclovir hydrate was prepared from the crystallization from water. The Examiner took a position that if the famciclovir subjected to crystallization from water contained even a trace amount of methanol, steps a) through c) of claim 35 would have been conducted by Harnden 1990. The Examiner also took a position that the famciclovir used by Harnden 1990 was prepared according to Harnden 1989 (Journal of Medicinal Chemistry, 1989, 32:1738-1743), and Harnden 1989 discloses a process of preparing famciclovir via hydrogenation of a 6-chloro intermediate (page 1741, right column, the 8th line from the bottom, to page 1742, left column, line 8, converting Derivative 13 to Derivative 14, Harnden 1989). The Examiner took a position that the famciclovir prepared by Harnden 1989 would contain at least a trace amount of methanol.

Applicants respectfully disagree. Applicants contend that Harnden 1989 discloses a process of preparing famciclovir requiring two steps of solvent removal, which would remove all methanol for all practical purposes. The Examiner, however, was not persuaded by the arguments of the applicants. Applicants will file a Rule 132 Declaration shortly showing experimental data that the reproduction of the process of Harnden 1989 resulted in a solid famciclovir containing no detectable methanol.

Withdrawal of the anticipatory rejection is requested.

In addition, since Harnden 1989 does not disclose the preparation of crystalline famciclovir by recrystallization from methanol, applicants submit that the methanol solvate of famciclovir is novel.

(B) Applicants also respectfully traverse the anticipatory rejections of claims 1-3, 5-10, 18, 19, 31, 37-40 and 43 over Harnden 1989 (*J. Med. Chem.* (1989) 32: 1738-1743); US 5,017,701; US 5,066,805; US 5,138,057; US 6,846,927; US 6,342,603; Freer (*Tetrahedron* (2000) 56:4589-4595); Geen (*Tetrahedron*, Vol. 46, pp. 6903-6914, 1990), US 6,437,125 and WO 2000/06573. Claim 43 had been cancelled previously. The cancellation of claims 1-3, 5-7, 8-10, 19, 31 and 37-40 has rendered the rejections of these claims moot. Applicants submit that

claim 18 was not anticipated by the cited prior art because none of the cited references discloses the trituration of famciclovir in isopropyl alcohol or acetonitrile to produce crystalline famciclovir characterized by a XRD pattern with peaks at 15.5 and 15.9 ± 0.2 deg. 2θ. Withdrawal of the anticipatory rejections is requested.

Conclusion

With the above reasoning, applicants submit that the application is in a condition for allowance. The Examiner is urged to contact the undersigned by phone if there remains any minor issues.

In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee and any other fees that may be required in relation to this paper can be charged to Deposit Account No. 11-0600 referencing Attorney Docket No. 01662/60903.

Respectfully submitted,

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Dated: April 20, 2009

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